

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

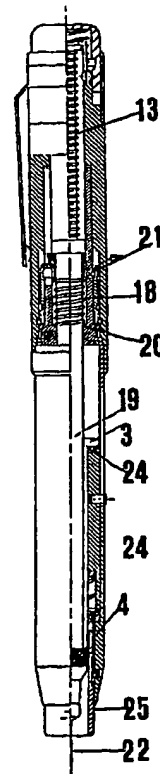
PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61M 5/20	A1	(11) International Publication Number: WO 94/13342 (43) International Publication Date: 23 June 1994 (23.06.94)
(21) International Application Number: PCT/IT92/00166 (22) International Filing Date: 18 December 1992 (18.12.92) (30) Priority Data: RM92A000881 11 December 1992 (11.12.92) IT (71)(72) Applicant and Inventor: GRECO, Ermanno [IT/IT]; Viale Liegi, 6, I-00198 Roma (IT). (74) Agent: SNEIDER, Massimo; Studio Tecnico Lenzi, Via Lucania, 13, I-00187 Rome (IT).		(81) Designated States: AT, AU, BB, BG, BR, CA, CH, CS, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i>

(54) Title: A DEVICE PRESET FOR THE AUTOMATIC INTRADERMAL ADMINISTRATION OF A DRUG**(57) Abstract**

The device preset for the automatic intradermal administration of a drug consists of a pen-shaped body formed of a bottom part (1) and a top part (2) joined together by means of a screw or a bayonet or a similar joint; the pressure applied to a button (5) frees a piston (19), to which a force is imparted by means of a preloaded spring (13), which strikes and pushes the plunger (4) of a syringe (3) housed in the bottom part (1) of the device and loaded with the drug required by the patient, thus causing the syringe needle to come out of the tip and inject the drug.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

Description

"A DEVICE PRESET FOR THE AUTOMATIC INTRADERMAL
ADMINISTRATION OF A DRUG"

* * * *

5 Background Art

For several years now some specialized firms have devised and marketed devices housing a syringe of a predetermined size, which may be previously loaded with the drug required by the patient and kept ready for use.

10 Said devices are generally cylinder-shaped and resemble a pen enabling the intradermal injection of the drug, thanks to the special mechanisms housed inside.

The devices briefly described above have proved very useful because, as previously mentioned, they enable a
15 person to have a loaded syringe always ready at hand, to be used whenever required.

Devices of the aforesaid type marketed to date, however, present a series of drawbacks which may jeopardize their safe operation.

20 Some of the marketed devices, for example, have had problems with the releasing mechanism of the small piston, which determines the injection of the drug, and with the safety lock, which prevents the accidental

release of said piston; furthermore, it has been seen that, in order to achieve optimal working conditions of the device, it is necessary to prevent even the smallest movement of the syringe inside the container, during both
5 the preparation of the device (loading the device with the syringe and reassembly of the component elements) and the injection of the drug. Furthermore, it has also been seen that it is necessary to modify the needle depth regulation system, besides providing for a mechanism
10 allowing the automatic return of the needle inside the container after use, in accordance with the new legislation on this matter.

The previous patent application filed by the same patent holder describes a device the body of which
15 resembles a pen and the inside of which houses a syringe loaded with the required drug; said device, although functional, nevertheless also presents the aforesaid drawbacks.

Disclosure of Invention

The object of this invention is a device specifically preset for the automatic intradermal administration of a drug, which remedies the aforesaid drawbacks, allowing a
5 considerable improvement of its functionality.

The device described herein essentially consists of a pen-shaped container, preferably made of a plastic material and made up of two parts joined the one to the other by means of a bayonet or screw joint.

10 The top part of the device houses the piston which drives the syringe plunger, the springs allowing this operation and the safety mechanisms which enable the return of the syringe needle inside the bottom part.

In the bottom part of the device there is the syringe
15 housing, which is provided with a coaxial sliding element, which moves along the longitudinal axis of the device.

This sliding element tends to be held up by a spring placed between the bottom part of the element itself and
20 the bottom part of the device, the tip of which is shaped like a truncated cone. A small lever, accessible from the outside, which moves inside a slot and is integral with the sliding element, allows the preparation of the syringe for the injection by removing the small cap which
25 protects the needle.

The foregoing brief description may be better understood by reading the more detailed description which follows, with reference to the attached drawings, in which:

5 fig. 1 shows a sectional view of the top part of the device and, in particular, of the safety mechanism;

 fig. 2 shows the horizontal section of a detail of the safety mechanism;

 figs. 3, 4 and 5 show a sectional view of the
10 releasing mechanism sequence;

 fig. 6 shows the mechanism which stops the syringe inside the lower part of the device;

 fig. 7 shows a sectional view of the entire device, with the position of the automatic syringe return
15 mechanism, during the injection;

 fig. 8 shows a sectional view of the entire device with the position of the automatic syringe return mechanism after the injection; lastly,

 figs. 9 and 10 show a sectional view of two positions
20 of the automatic syringe return mechanism.

 As previously mentioned, the device described herein is very useful for those patients who require injections at very short notice, without having to carry around a syringe with the drug to be injected. In order to work
25 correctly the device described herein, as also those

already on the market, must be prepared beforehand with the drug and set in such a manner as to be immediately usable whenever required.

In order to prepare the device it is first of all
5 necessary to separate the two component parts, i.e., the bottom part 1 shown in fig. 6, from the top part 2, shown in fig. 1. As previously described, these two elements are joined together by means of a screw or bayonet joint. The bottom part 1 houses the syringe 3 which, having been
10 loaded beforehand with the required drug, presents the plunger 4 ready to inject the drug through the needle. In order to prevent the syringe from making even the slightest movement inside the container 1 there are two ring-shaped or similar gaskets 24 made of rubber and
15 placed inside suitably deep cuts made at angles of 120 degrees the one to the other; said location of the gaskets 24 ensures that the syringe 3 may be placed inside the container 1 without having to exert an excessive pressure thanks to the elastic nature of the
20 gaskets, which also keep the syringe in place during the preparatory phase, preventing it from accidentally moving down or from making any movement whatsoever during the injection. A third gasket 24 is also placed in a specific cut between the top part of the syringe 3 and the edge of
25 its housing, in order to prevent any damage to the top

part of the syringe when the piston starts pushing the plunger and the syringe reaches its lower counterboring.

When the syringe 3 has been loaded and the rod (not shown) enabling the manual working of the plunger 4 has
5 been unscrewed, said plunger 4 will find itself at the end of the thread of the bottom part of the container. After having placed the syringe 3 in its housing and before loading the piston 19 which will push the plunger 4 of the syringe 3 during the injection, it is necessary
10 also to prepare the system which will allow the automatic return of the syringe 3 after the injection.

The automatic return mechanism of the syringe is shown in figs. 7, 8, 9 and 10.

Fig. 7 shows the spring 18 in its preloaded position, said preloading having been achieved by pulling down the
15 piston 19, before pushing it upwards for loading the spring 13, which pushes the piston 19 when the drug must be injected.

The spring 18, which enables the return of the
20 syringe and, therefore, the return of the needle 22 inside the device, is kept compressed after the loading, between the counterboring 20 and the backstop 21, assisted in its action by the spherical element 21'. When, as shown in fig. 7, the piston 19 has pushed the
25 plunger 4 of the syringe up to the end of its stroke,

i.e., at the end of the injection, the top of the piston 19 causes the backstop 21 to move, thus freeing the previously compressed spring 18 which, taking on the position shown in fig. 8, pulls up the syringe 3 and, consequently, the needle 22 also, which is hidden inside the device, preventing any further accidental contact.

The traction of the piston 19, therefore, precedes the compression of the piston 19, which is required to load the spring 13 and set the device for working automatically when the cap 5 is pressed. The pressure on the cap 5 frees the spring 13 which then discharges its compressed strength onto the piston 19 which pushes the plunger 4, as previously described, and, consequently the syringe 3 and the needle 22 out of the device, thus executing the injection.

In order to prevent the accidental triggering of the cap 5, a safety lock shown in figs. 1 and 2 has been provided for. These figures clearly show that a pin 7 is attached to the cap 5 which, in the safety lock position, engages in the horizontal part 9 of the slot 8 (shown in the fig. 2), provided for on the inside body to which the cap 5 is fixed but free to rotate; when it is in this position, even if the cap 5 is pressed it will not move. By rotating the cap 5 for a certain angle, the pin 7 moves to the vertical part 10 of the slot 8 and,

therefore, the cap 5 is free to move downwards when pressed.

5 The slot 8 ends on the left side with a vertical groove which acts as a sort of stop and which obliges the user to exert a light pressure in order to return to the previous position.

10 Once the safety lock has been removed by rotation, the cap 5, when pressed, moves down automatically triggering the mechanism illustrated in figs. 3, 4 and 5. As may be seen in fig. 3, when the cap 5 is in the safety position the spherical element blocks the backstop 12, at the top end of the piston 19, thus forcing the spring 13 to remain compressed; the pressure on the cap 5 makes sure that the spherical element 11, pushed by the particular
15 shape of the top end 12 of the piston 19, moves into the housing 14, which it encounters in its path during its movement downwards, enabling the piston 19, pushed by the spring 13, to discharge all its strength onto the plunger 4 of the syringe 3 causing with a single movement the
20 exit of the needle from the device and the intradermal injection of the drug into the patient.

It is possible to vary the amount of the needle which comes out of the device and, therefore, the depth of penetration of the same by means of a thread between the
25 runner 25 and the tip of the device.

C L A I M S

1. A device specifically preset for the automatic intradermal administration of a drug, with a pen-shaped body consisting of a bottom and a top part joined together by means of a screw or a bayonet or similar joint; the pressure applied to a button frees a piston, to which a force is imparted by means of a preloaded spring, which strikes and pushes the plunger of a syringe housed in the bottom part of the device and loaded with the drug required by the patient, thus causing the syringe needle to come out of the tip and inject the drug.

2. A device specifically preset for the automatic intradermal administration of a drug, as per claim 1, characterized by the fact that the piston 19, which pushes the plunger 4 of the syringe 3, before being pushed in order to compress the spring 13 which enables it to perform the injection when the patient pushes the releasing button, is pulled in order to compress the spring 18, which remains in such a position of compression until the top part of the piston 19, as soon as said piston has finished pushing the plunger 4 of the syringe 3, determines the movement of the backstop 21 and the consequent liberation of the spring 18 which pulls the entire syringe 3 and, consequently, the needle 22,

back inside the device.

3. A device specifically preset for the automatic intradermal administration of a drug, characterized by the fact that a safety lock has been specifically
5 provided for, in order to prevent the accidental triggering of the releasing mechanism of the piston 19, once said mechanism has been loaded and the syringe containing the drug has been inserted in its housing in the bottom part of the device; said safety lock consists
10 of a pin 7 attached to the cap 5, the latter functioning as a releasing button. The pin 7, in the safety position, engages in the horizontal part 9 of the slot 8 provided for inside the part of the device to which the cap 8 is fixed although free to rotate; by rotating the cap 5 the
15 pin 7 meets the vertical part 10 of the slot 8 and overcoming the weak resistance offered by the spring 23 the piston 19 releasing mechanism is triggered.

4. A device specifically preset for the automatic intradermal administration of a drug, as per the previous
20 claims, characterized by the fact that the downwards movement of the cap 5 triggers the releasing mechanism of the piston 19; in the safety position of the cap 5 the spherical element 11 blocks the backstop 12 forcing the spring 13 which drives the piston 19 to remain in a
25 compressed position, the pressure on the cap 5 determines

that the spherical element 11 pushed by the top obliquely-shaped part of the piston 19 move into the specific housing 14 leaving the piston 19 driven by the spring 13 the possibility of unloading its strength on the plunger 4 of the syringe 3, thus causing, with a single movement, the ejection of the needle 22 from the hole specifically provided for at the tip of the device and the injection of the drug caused by the plunger 4 of the syringe 3, pushed by the piston 19.

5. A device specifically preset for the automatic intradermal administration of a drug, characterized by the fact that, in order to prevent even the slightest movement of the syringe inside the device, rubber ring-shaped or similar gaskets have been introduced inside specific housings in the lower part of the device, housings consisting of cuts made at 120 degrees the one from the other, so as to maintain a considerable degree of elasticity. A further gasket has been provided for between the upper part of the syringe 3 and the edge of the syringe housing, so as to prevent any damage to the upper part of the syringe when the piston starts pushing the plunger and the syringe reaches the lower counterboring.

1/5

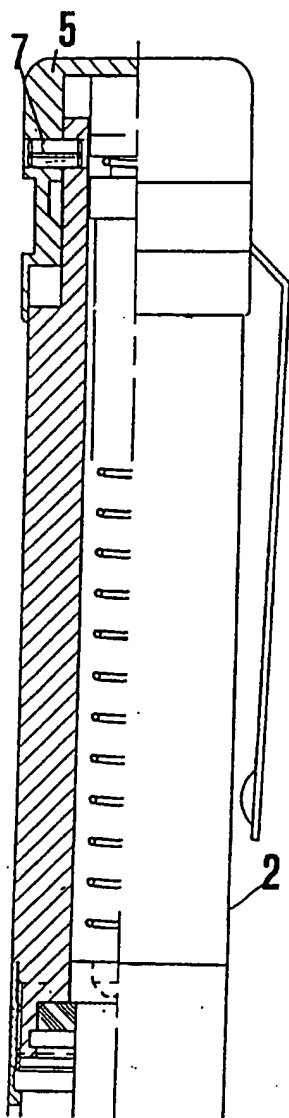


FIG 1

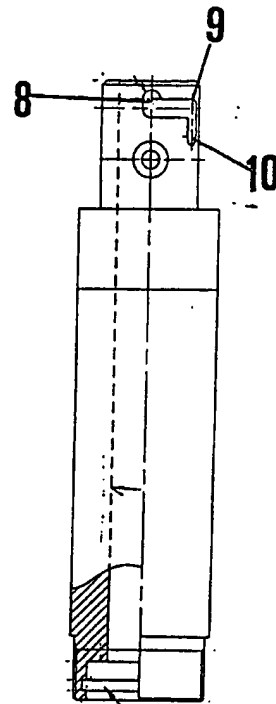
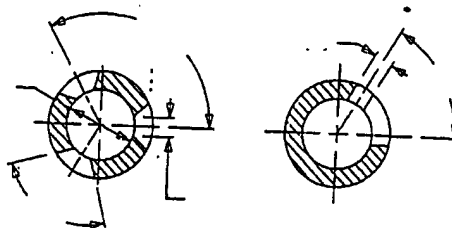


FIG 2



2/5

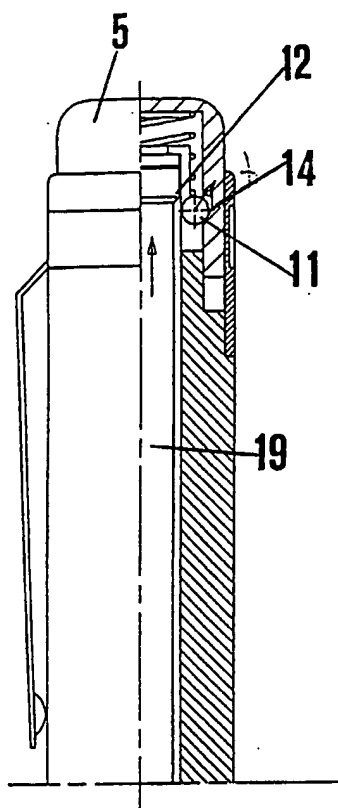
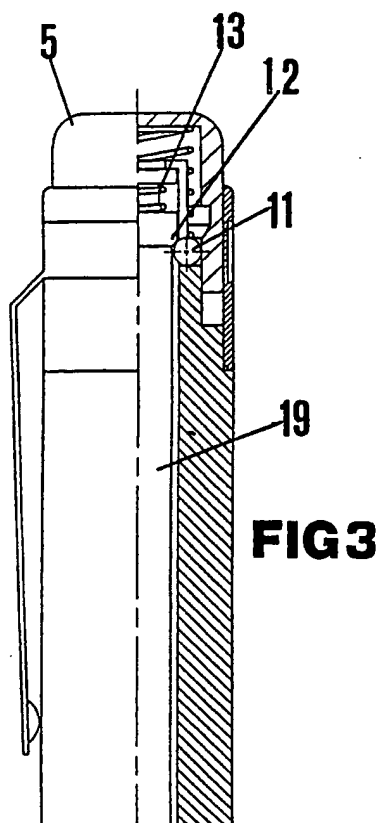


FIG 4

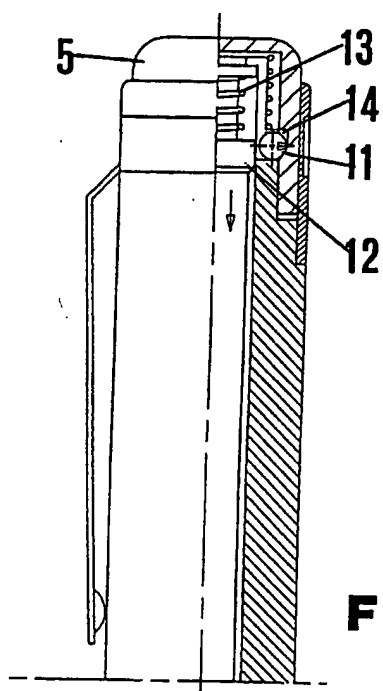


FIG 5

3/5

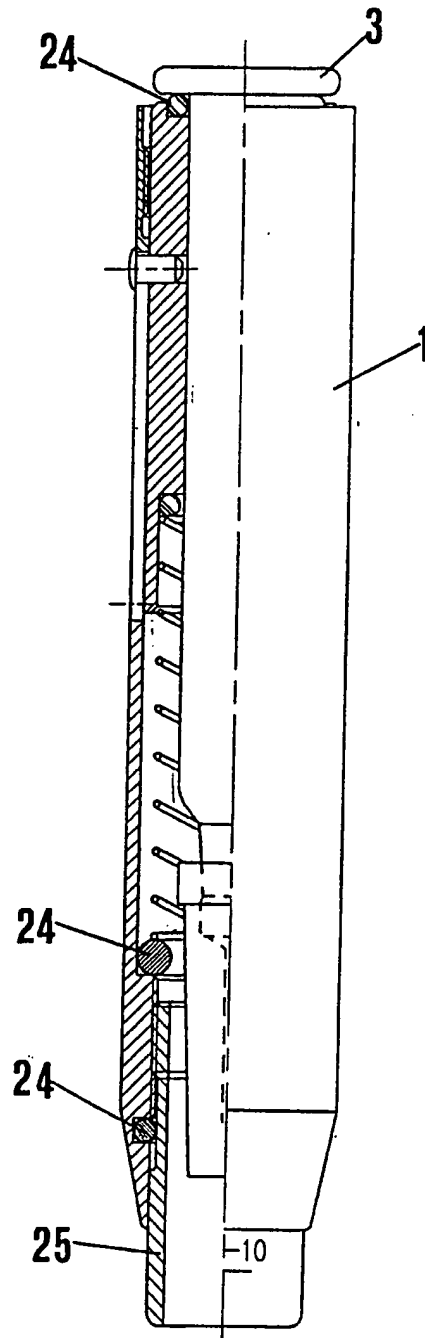


FIG 6

4/5

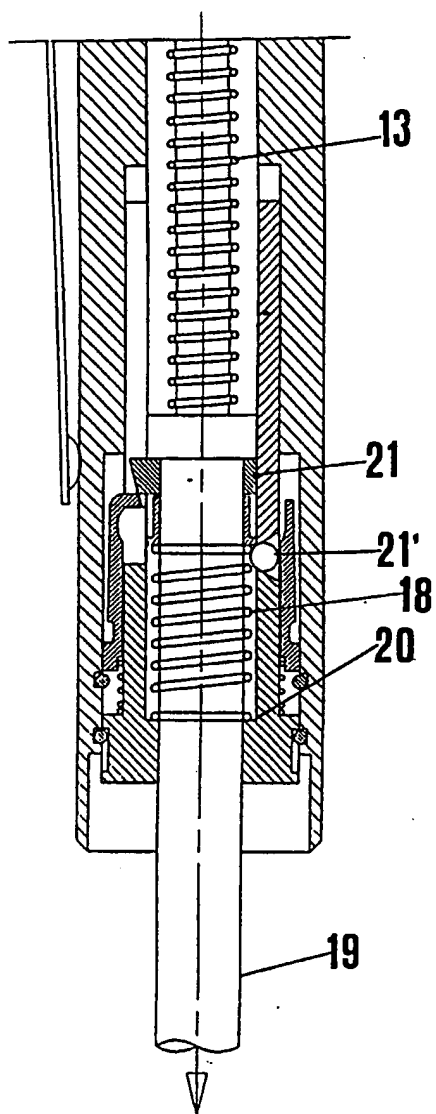


FIG 9

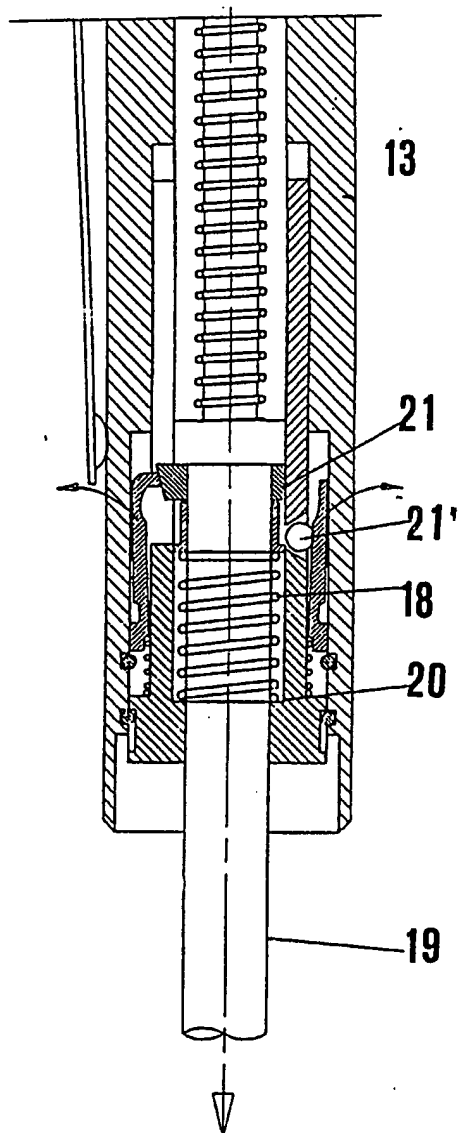


FIG 10

5/5

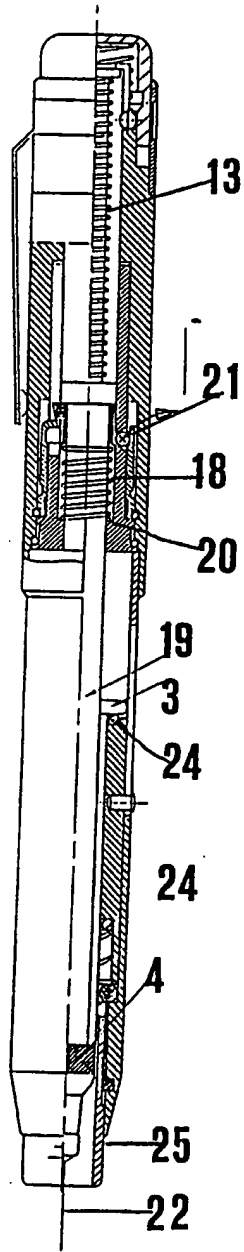


FIG 7

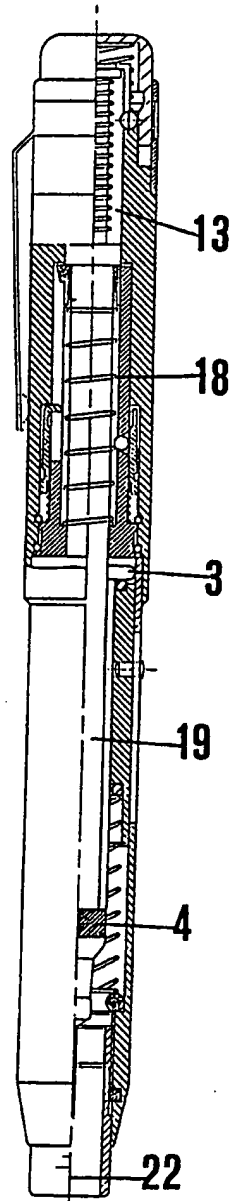


FIG 8

INTERNATIONAL SEARCH REPORT

PCT/IT 92/00166

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61M5/20		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61M	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	EP,A,0 516 473 (OWEN MUMFORD LIMITED) 2 December 1992 see column 2, line 26 - column 4, line 31 see figures 1-4	1
Y		4
A		2
Y	DE,U,8 333 718 (MAURER) 15 May 1986 see page 6, line 14 - page 9, line 2 see figures 1,2	4
X	US,A,4 316 463 (SCHMITZ ET AL.) 23 February 1982 see column 2, line 66 - column 3, line 30 see figures 3-7	3
	--- -/--	
<p>¹⁰ Special categories of cited documents :¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
23 JULY 1993	17.08.93	
International Searching Authority	Signature of Authorized Officer	
EUROPEAN PATENT OFFICE	SCHOENLEBEN J.	

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X	EP,A,0 268 191 (WILHELM HASELMEIER GMBH & CO) 25 May 1988 see column 4, line 31 - column 6, line 55 see column 10, line 36 - column 11, line 53 see figures 1,2 ---	1
A	US,A,4 717 384 (WALDEISEN) 5 January 1988 see column 4, line 25 - line 36 see figure 3 -----	5

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

IT 9200166
SA 68844

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 23/07/93

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0516473	02-12-92	None	
DE-U-8333718	15-05-86	None	
US-A-4316463	23-02-82	None	
EP-A-0268191	25-05-88	DE-A- 3638984	26-05-88
		JP-A- 63139563	11-06-88
		US-A- 5114406	19-05-92
US-A-4717384	05-01-88	None	